K130565

## 510(k) Summary

This summary of the 510(k) premarket notification for the NIDEK Specular Microscope CEM-530 is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

**Date Prepared:** November 27, 2013

**SPONSER/ 510(k) OWNER/ MANUFACTURER**

NOV 27 2013

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**NAME OF DEVICE**

Trade Name: CEM-530
Common Name: Specular Microscope

**DEVICE CLASSIFICATION/FDA REVIEWING BRANCH**

The Ophthalmic Branch has classified AC Powered Slit Lamp Biomicroscopes as Class II devices pursuant to 21 C.F.R. §886.1850.

**PRODUCT CODE: CLASSIFICATION / CFR TITLE**

NQE, 21 CFR 886.1850

**PREDICATE DEVICE**

Konan Medical, Inc. Cellchek Plus (K120264)

## INDICATIONS FOR USE

The Nidek Specular Microscope CEM-530 is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

## PRODUCT DESCRIPTION

The Nidek Specular Microscope CEM-530 provides non-contact, high magnification image capture of the endothelium enabling observation of the size and shape of cells. Information such as the number of endothelial cells, cell density, and cell area is analyzed through the captured images. The captured images and analysis results of the endothelium are used in intraocular or corneal surgery, postoperative follow-up, and corneal observation such as for endothelial disorders or the corneal state of patients who wear extended-wear contact lenses. Observation is possible in the central area (visual angle: 5°) and peripheral area (visual angle: 27°) using a periphery capture function as well as in the center of the cornea. The captured images and analysis results can be printed on the built-in printer or optional video printer, or output to an external device over LAN connection. In addition to the specular microscopy, the corneal thickness can be optically measured in a non-contact method. The CEM-530 has auto-tracking and auto-shooting functions. Results can be printed using the the built-in thermal printer or captured images can be transferred to a filing system via LAN connection.

## SUBSTANTIAL EQUIVALENCE

The Specular Microscope CEM-530 is substantially equivalent to the Konan Medical, Inc. Cellchek Plus (K120264). The Specular Microscope CEM-530 has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicate device. Clinical performance data is provided which demonstrates that the CEM-530 is substantially equivalent to the Konan predicate device.

The CEM-530 and the predicate device are both non-contact ophthalmic microscopes, optical pachymeters, and cameras intended for examination of the corneal endothelium and for measurement of the thickness of the cornea. Both the CEM-530 and the predicate device offer automatic capture features and manual capture modes. Both the CEM-530 and the predicate device have a built-in CCD camera. Slight differences in flash, illumination for focusing and fixation lamps were evaluated in terms of light safety and found to meet the requirements of ISO 15004-2.

Both the CEM-530 and the predicate device include an optical pachymeter with an accuracy of $\pm$ 10 microns.

Regarding image analysis, both the CEM-530 and the predicate device offer automatic image analysis while the predicate device also offers manual analysis of images. Clinical performance data is provided which evaluates the precision and accuracy of the automatic analyses performed

by the CEM-530 compared to manual measurements performed with the predicate device. The clinical performance data demonstrates the substantial equivalence of the CEM-530 automatic measurement mode to the predicate device's manual mode.

Both the CEM-530 and the predicate device comply with applicable electrical safety and light safety standards.

**NON-CLINICAL PERFORMANCE SUMMARY**

The performance testing conducted using the NIDEK Specular Microscope CEM-530 verified that the device operates as intended. The specifications to which the CEM-530 was verified to are substantially equivalent to the predicate devices and therefore, support a determination of substantial equivalence. The pachymetry functionality was evaluated in model eyes and the measurement accuracy of $\pm$ 10 microns was confirmed.

Additionally, the CEM-530 was subjected to electrical safety testing in accordance with IEC 60601-1, electromagnetic compatibility (EMC) testing in accordance with IEC 60601-1-2, and optical radiation safety testing in accordance with ISO 15004-1 and ISO 15004-2.

**CLINICAL PERFORMANCE SUMMARY**

A prospective clinical study was conducted to assess the agreement, accuracy and precision of the CEM-530 by comparing results across three machines/operators to those obtained with the predicate device, the Cellchek Plus. Three populations were studied: young (18-28 years of age) and adult (29-80 years of age) healthy subjects and pathologic adult eyes (29-80 years of age).

A total of 74 eyes were evaluated (24 non-pathologic young eyes, 25 non-pathologic adult eyes, and 25 pathologic adult eyes) for the assessment of device agreement and 62 evaluable eyes (20 non-pathologic young eyes, 22 non-pathologic adult eyes, and 20 pathologic adults eyes) for the assessment of device precision.

All evaluable study eyes (74 eyes) were included in the assessment of device agreement. The differences were on the order of 3-5% of the overall mean value for endothelial cell density, coefficient of variation of endothelial cell area, and central corneal thickness measurements and approximately 15% of the overall mean for % hexagonality. All of the 95% Limits of Agreement (LOAs) included 0 and the majority was well centered around 0. However, for % hexagonality, the measurements for the CEM-530 device were generally higher than those from the Cellchek Plus machine. The correlation coefficients were generally high for the endothelial cell density and central corneal thickness measurements, indicative of strong linear relationships; but they were low for coefficient of variation of endothelial cell area and % hexagonality.

The mean differences for endothelial cell density are illustrated on the Bland Altman plot (Figure 1. The greatest absolute differences between the two machines were seen at the extremes of the measurement range (Figure 2). The Deming regression line (Figure 3) showed good agreement between the devices. Table 1 provides a summary of the agreement data for all subjects.

**Endothelial Cell Density**

**Figure 1: Bland-Altman Plot- Observed Data-Endothelial Cell Density- All Subjects, Effectiveness Population**

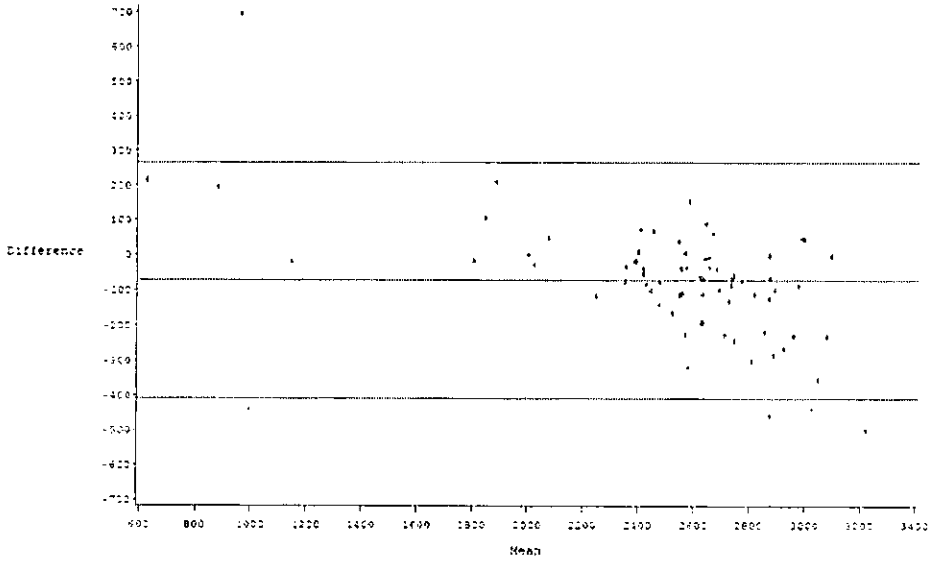



**Figure 2: Device Difference by Cellchek Plus Value- Endothelial Cell Density- All Subjects, Effectiveness Population**

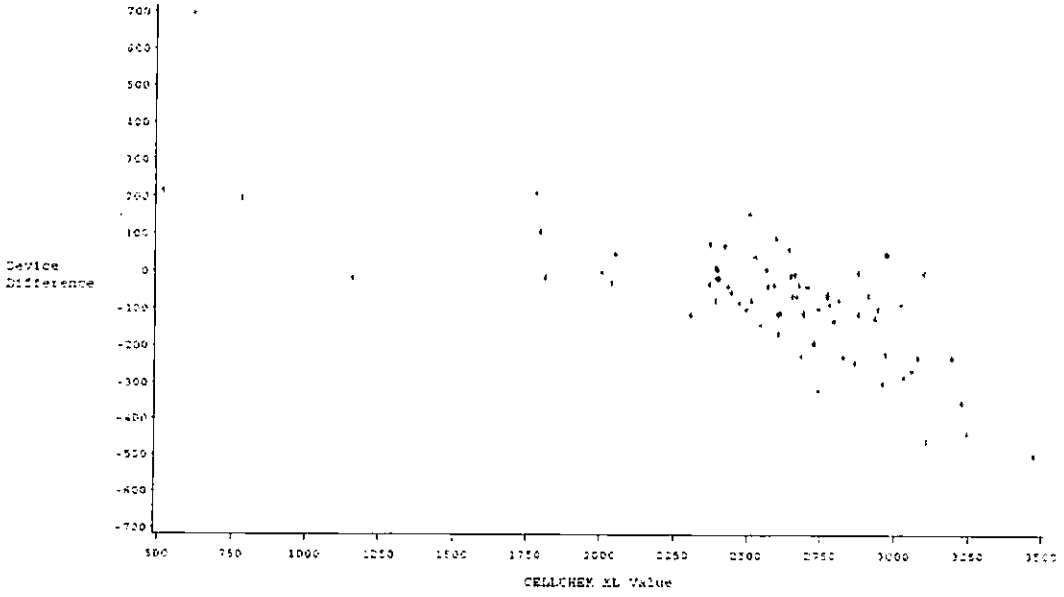


**Figure 3: Deming Regression Plot- CEM-530 by Cellchek Plus- Endothelial Cell Density- All Subjects, Effectiveness Population**

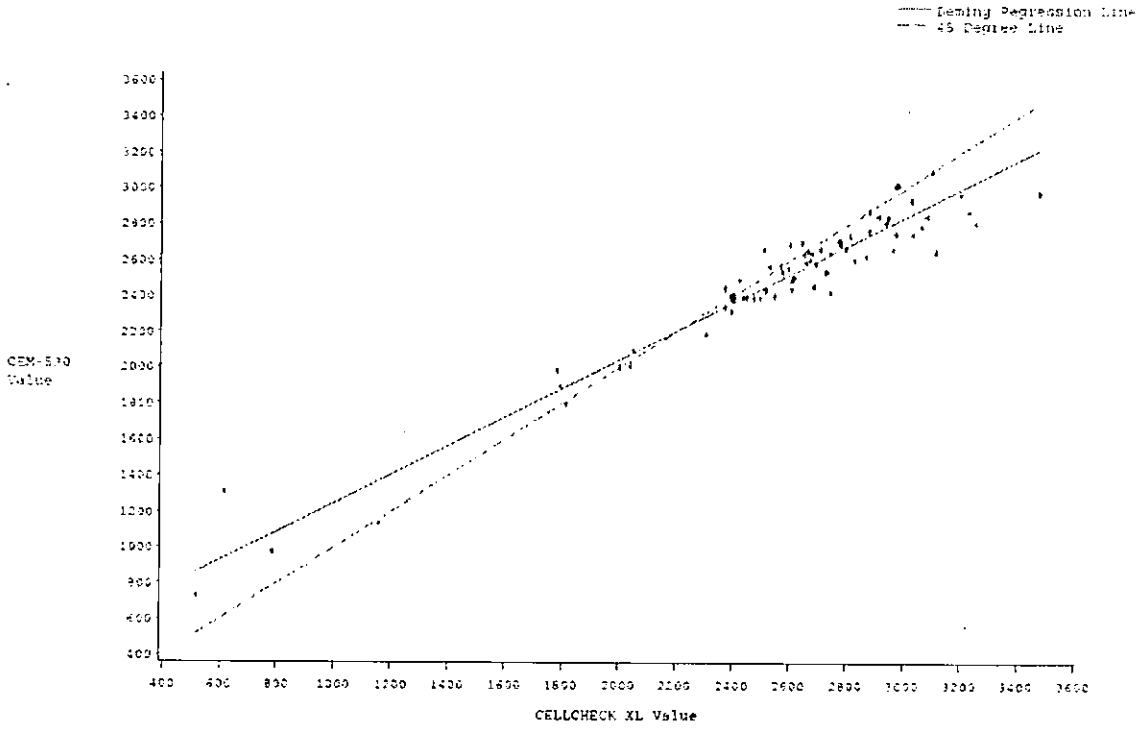


**Table 1: Four Corneal Specular Microscopic Variables Assessed with the Two Devices, All Configurations, All Subjects, Effectiveness Population**

| | Endothelial Cell Density | Coefficient of Variation Endothelial Cell Area (CV) | Coefficient of Variation Endothelial Cell Area WITHOUT Subject 001-3-008 | % Hexagonality | Central Corneal Thickness |
|---|---|---|---|---|---|
| **Nidek CEM-530** | | | | | |
| N | 74 | 74 | 73 | 74 | 74 |
| Mean (SD) | 2482.6 (436.55) | 29.9 (7.21) | 29.4 (5.86) | 69.0 (5.19) | 551.5 (40.7) |
| Median | 2574.0 | 28.0 | 28.0 | 69.0 | 551.0 |
| Min-Max | 731 - 3093 | 19 - 66 | 19 - 52 | 56 - 82 | 411 - 640 |
| Deming Regression Intercept (95% Confidence Interval) | 452.8 (193.1, 712.5) | 3278.7 (-120246.9 , 126804.3) | -42.2 (-90.2, 5.8) | 55.3 (38.0, 72.5) | -4.2 (-120.5, 112.2) |
| Deming Regression Slope (95% Confidence Interval) | 0.8 (0.7, 0.9) | -104.3 (-4072.4, 3863.8) | 2.3 (0.7, 3.8) | 0.2 (-0.1, 0.5) | 1.0 (0.8, 1.2) |
| **Konan CELLCHEK XL (PLUS)** | | | | | |
| N | 74 | 74 | 73 | 74 | 74 |
| Mean (SD) | 2553.1 (544.85) | 31.2 (4.63) | 31. 4 (4.00) | 59.3 (7.80) | 565.2 (41.32) |
| Median | 2649.5 | 31.0 | 31.0 | 59.5 | 565.0 |
| Min- Max | 515 - 3472 | 11 - 40 | 22 - 40 | 40 - 75 | 474 - 685 |
| **Device Comparisons** | | | | | |
| Mean Difference (SD) | -70.5 (167.89) | -1.3 (8.60) | -2.1 (5.52) | 9.7 (8.44) | -13.8 (19.63) |
| Mean Difference (SD) as a % of the CELLCHEK reading | -0.42% (15.416%) | 0.77% (61.409%) | -6.07% (17.73%) | 18.19% (17.464%) | -2.38% (3.558%) |
| 95% Limits of Agreement (LOA) | (-406.3, 265.2) | (-18.5, 15.9) | (-13.1, 9.0) | (-7.2, 26.5) | (-53.0, 25.5) |
| Correlation ($R^2$) | 0.9654 | -0.0088 | 0.4247 | 0.2036 | 0.8856 |

***Coefficient of Variation of Endothelial Cell Area***

For the total population, the mean differences illustrated on the Bland Altman plot (Figure 4) were generally small. The flatness of the device difference plot (Figure 5) throughout the measurement range also illustrates good agreement between the devices, although an outlier is visible that had a low Cellchek Plus value and a very high Nidek CEM-530 value. This outlier caused a very poor fit on the Deming regression of Figure 6, but this greatly improved in Figure 7 when the regression lines were drawn with this subject excluded.

**Coefficient of Variation of Endothelial Cell Area**

**Figure 4: Bland-Altman Plot Observed Data- Coefficient of Variation Endothelial Cell Area- All Subjects, Effectiveness Population**

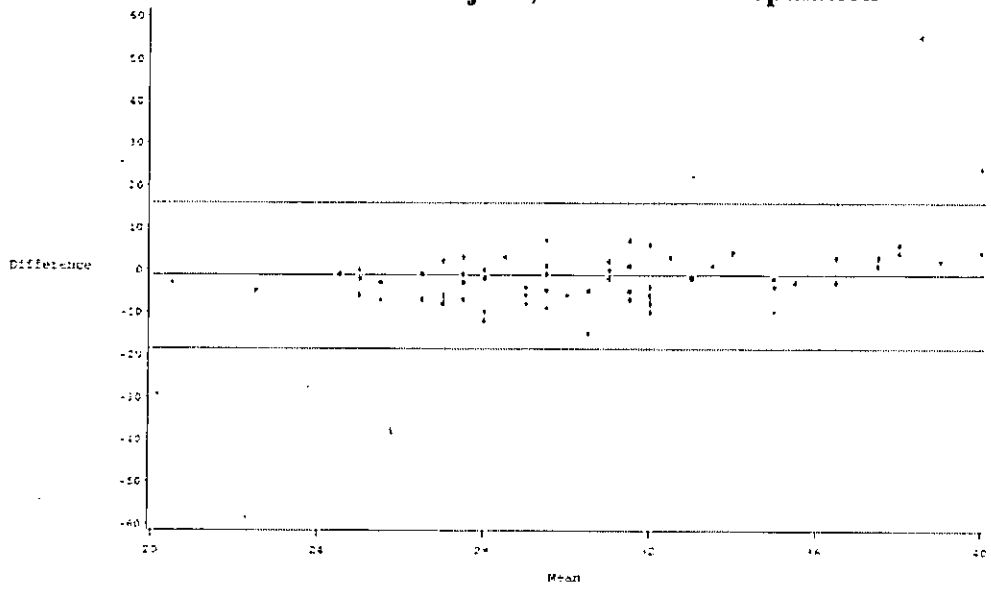


**Figure 5: Device Difference by Cellchek Plus Value- Coefficient of Variation Endothelial Cell Area- All Subjects, Effectiveness Population**

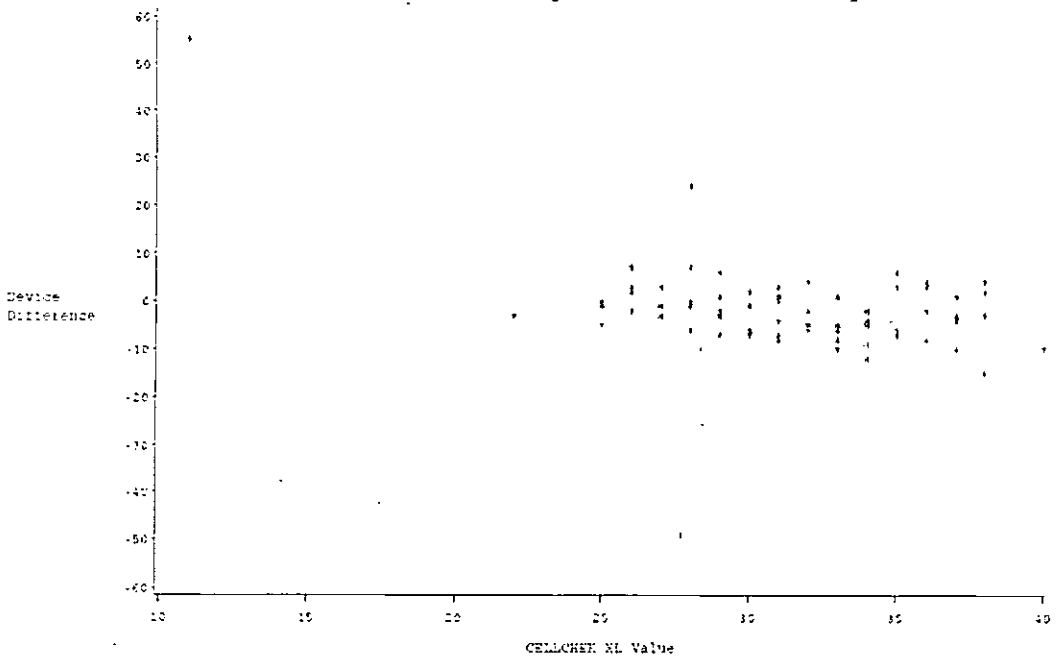



**Figure 6: Deming Regression Plot- CEM-530 by Cellchek Plus - Coefficient of Variation Endothelial Cell Area- All Subjects, Effectiveness Population, with Outlier**

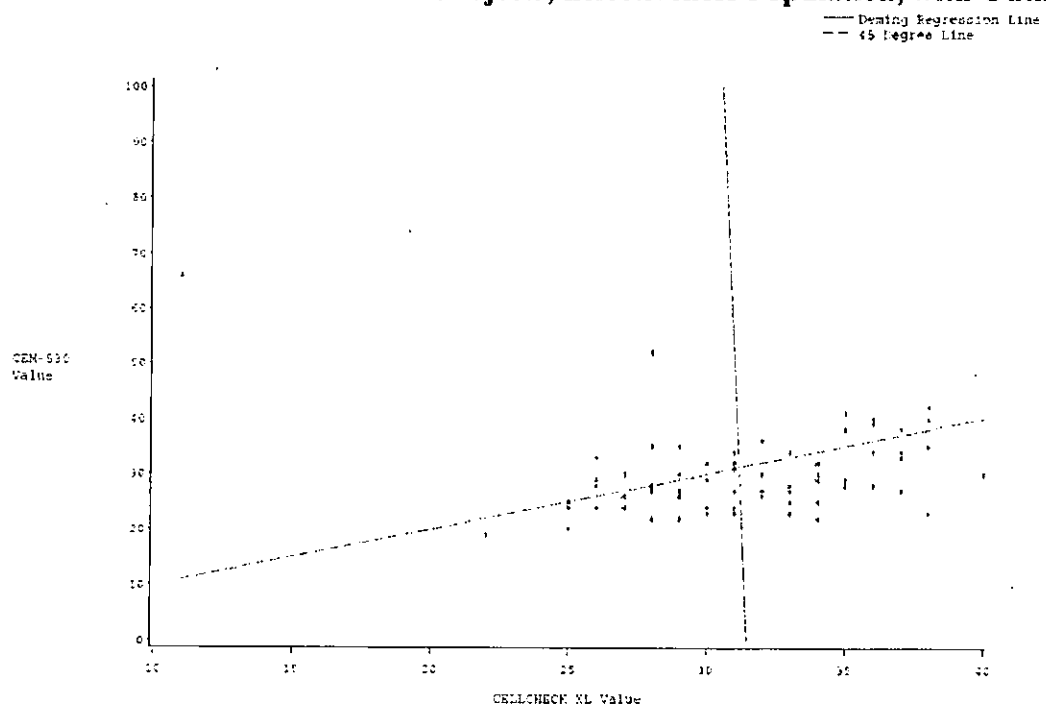
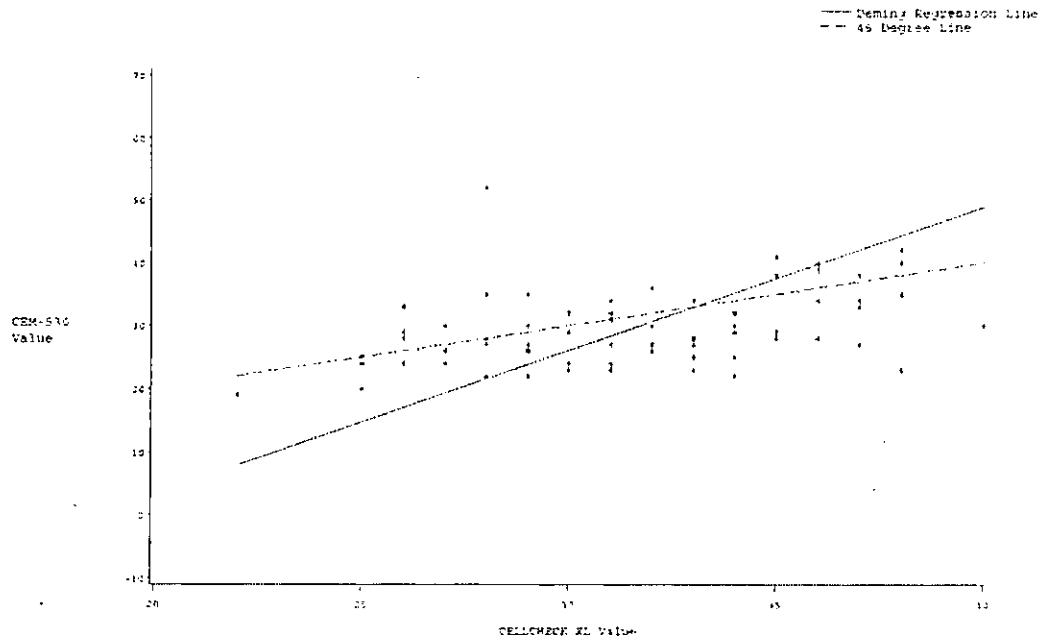


**Figure 7: Deming Regression Plot- CEM-530 by Cellchek Plus - Coefficient of Variation Endothelial Cell Area- All Subjects, Effectiveness Population, without Outlier**




***Percent Hexagonality***

While the LOAs included 0, the mean differences were on the order of approximately 15% of the mean for % hexagonality (Figure 8), more than for the other 3 variables. The lack of flatness of the device difference plot, Figure 9, also shows that the largest device differences are seen at the lower end of the scale. The Deming regression lines (Figure 10) show some agreement between the two devices.

**Percent Hexagonality**

**Figure 8: Bland-Altman Plot- Observed Data- % Hexagonality- All Subjects, Effectiveness Population**

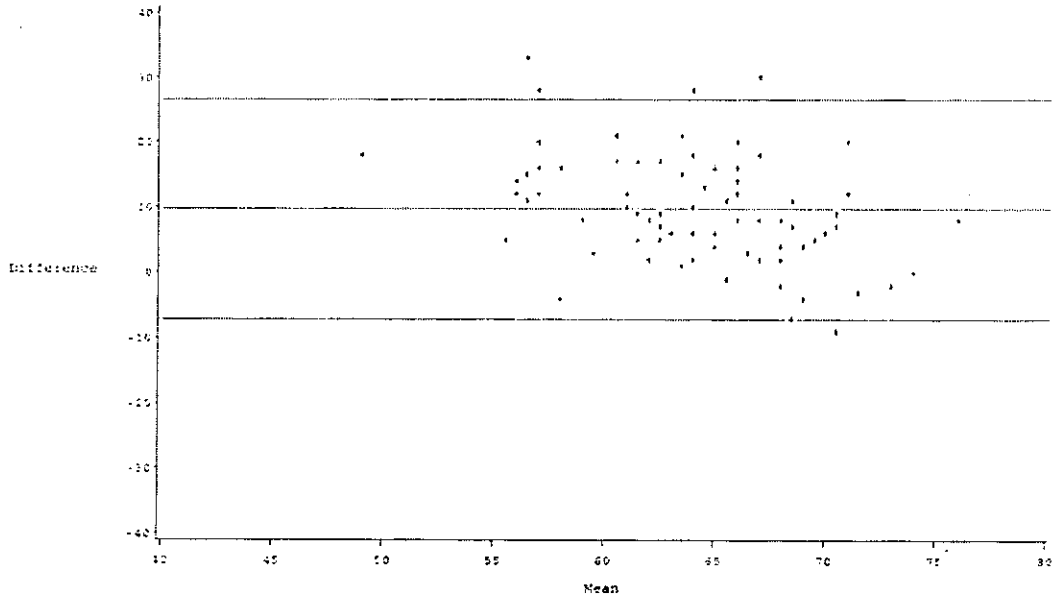



**Figure 9: Device Difference by CELLCHEK XL (PLUS) Value- % Hexagonality- All Subjects, Effectiveness Population**

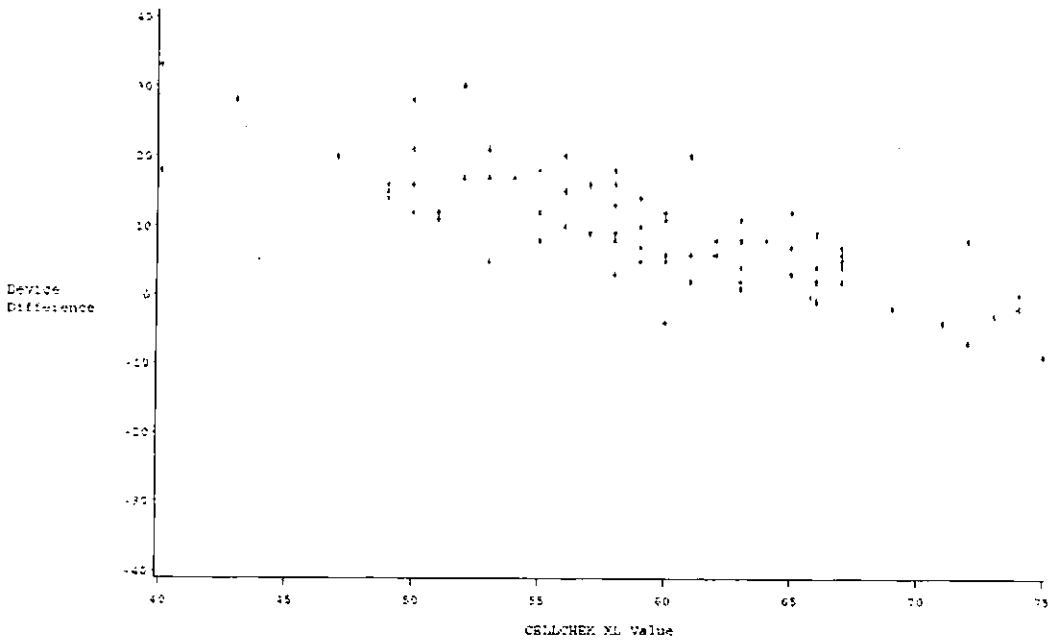
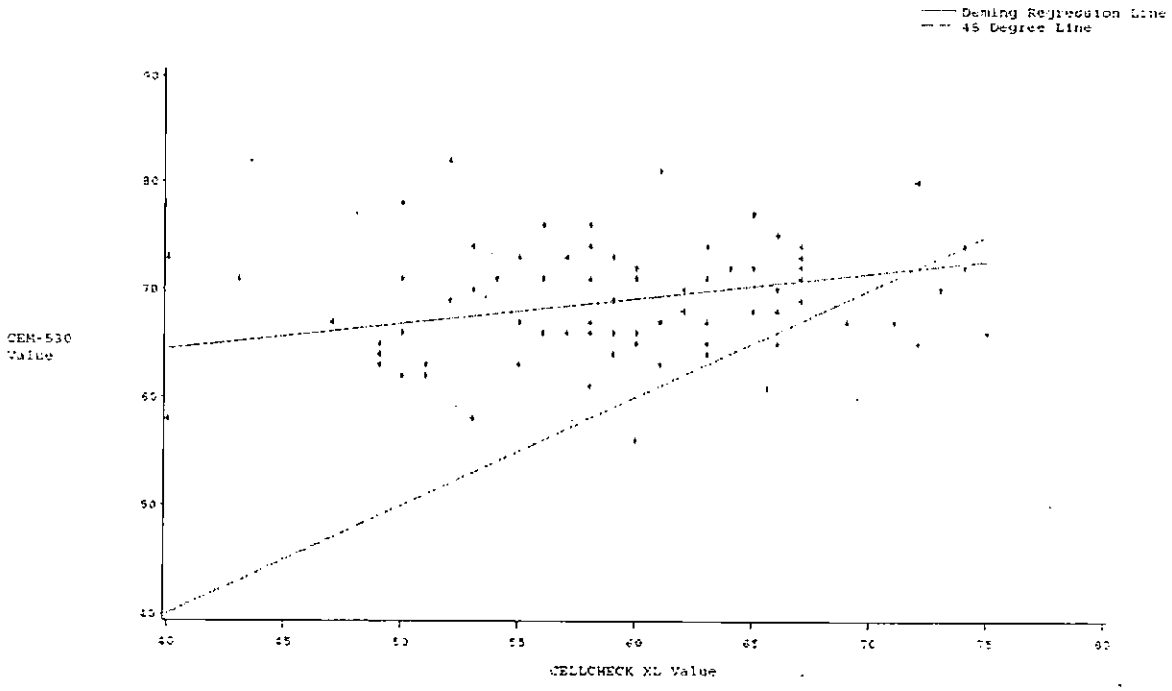


**Figure 10: Deming Regression Plot- CEM-530 by CELLCHEK XL (PLUS)- % Hexagonality- All Subjects, Effectiveness Population**




***Central Corneal Thickness***

The Bland Altman plot of Figure 11 shows that the LOAs include 0, indicating a lack of an overwhelmingly large systematic bias. The device differences plot (Figure 12) shows no notable effect of scale on agreement. The Deming regression lines (Figure 13) show an excellent fit.

**Central Corneal Thickness**

**Figure 11: Bland-Altman Plot- Observed Data- Central Corneal Thickness- All Subjects, Effectiveness Population**

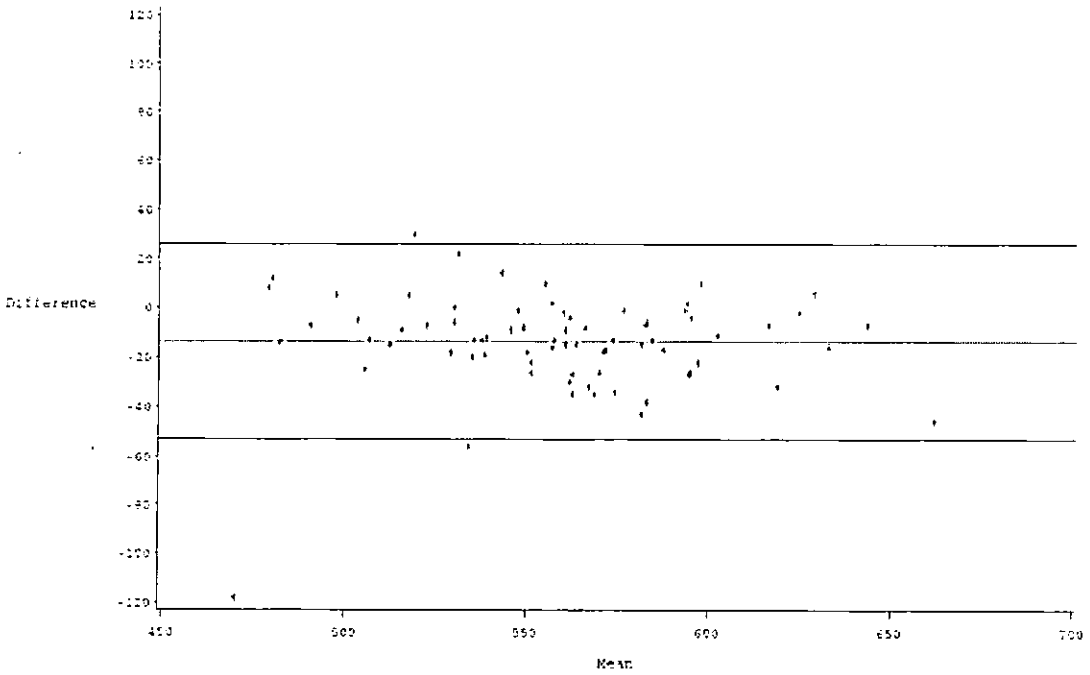



**Figure 12: Device Difference by Cellchek Plus Value- Central Corneal Thickness- All Subjects, Effectiveness Population**

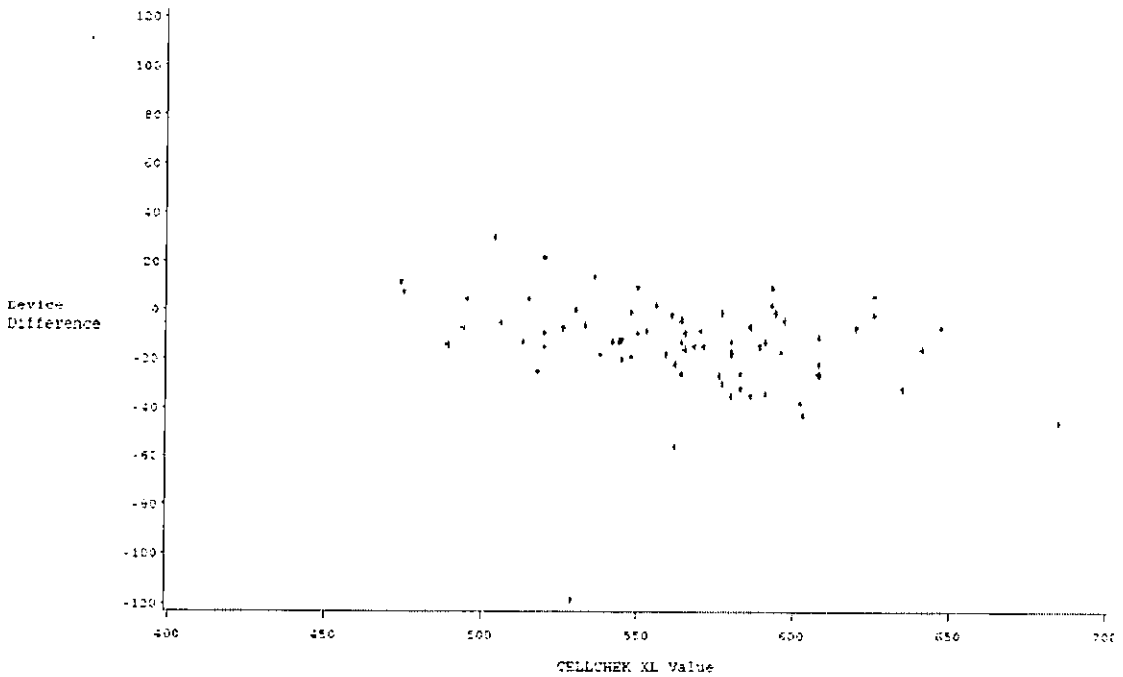
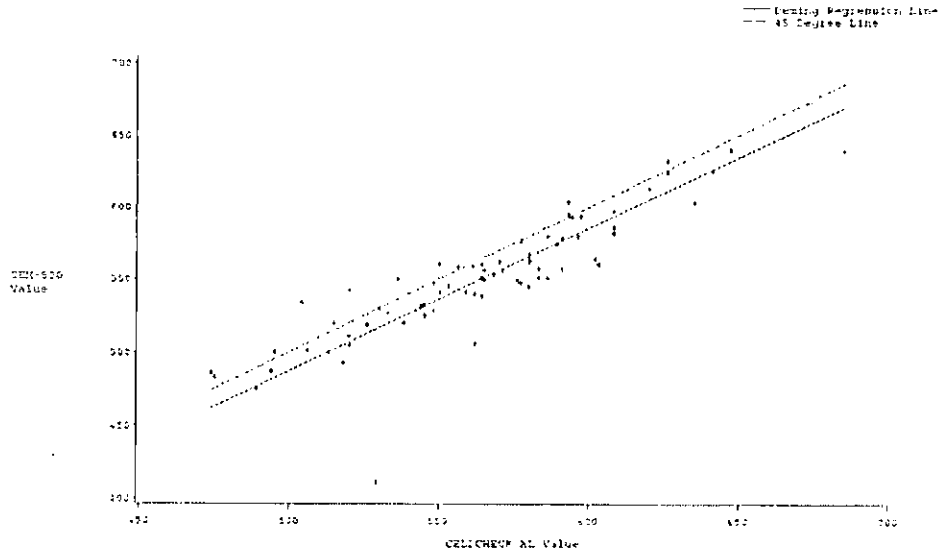


**Figure 13: Deming Regression Plot- CEM-530 by Cellchek Plus - Central Corneal Thickness - All Subjects, Effectiveness Population**



Agreement of the measurements with the CEM-530 and the predicate device was found to be acceptable. Overall, within eye/subject variability was acceptable, and similar for both machines.

The precision of the two devices was assessed with repeatability and reproducibility measures: the first within a given subject and the second within and among configurations. Table 2 shows the repeatability and reproducibility data for each of the 4 variables in all subjects. Repeatability was notably better for the CEM-530 device for central corneal thickness. The two devices had comparable repeatability for the other endpoints.

**Table 2: Precision Analyses- All Subjects Effectiveness Population**

| Variable | Nidek CEM-530 N=62 | Konan CELLCHEK PLUS N=62 |
|---|---|---|
| **Endothelial Cell Density** | | |
| Repeatability SD | 75.5 | 62.4 |
| Repeatability SD as a % of the Mean | 3.0% | 2.4% |
| Repeatability Limit | 211.5 | 174.8 |
| ***Repeatability Ratio (CEM-530/CELLCHEK PLUS)*** | ***1.2102*** | |
| Reproducibility SD | 113.2 | 95.2 |
| Reproducibility SD as a % of the Mean | 4.5% | 3.7% |
| Reproducibility Limit | 317.0 | 266.7 |
| ***Reproducibility Ratio (CEM-530/CELLCHEK PLUS)*** | ***1.1887*** | |

| Coefficient of Variation of Endothelial Cell Area (CV) | | |
|---|---|---|
| Repeatability SD | 2.3 | 2.7 |
| Repeatability SD as a % of the Mean | 8.1% | 8.5% |
| Repeatability Limit | 6.6 | 7.5 |
| ***Repeatability Ratio (CEM-530/CELLCHEK PLUS)*** | ***0.8746*** | |
| Reproducibility SD | 2.7 | 2.7 |
| Reproducibility SD as a % of the Mean | 9.3% | 8.6% |
| Reproducibility Limit | 7.6 | 7.6 |
| ***Reproducibility Ratio (CEM-530/CELLCHEK PLUS)*** | ***1.0016*** | |
| **% Hexagonality** | | |
| Repeatability SD | 4.1 | 5.4 |
| Repeatability SD as a % of the Mean | 6.0% | 8.8% |
| Repeatability Limit | 11.4 | 15.0 |
| ***Repeatability Ratio (CEM-530/CELLCHEK PLUS)*** | ***0.7586*** | |
| Reproducibility SD | 4.1 | 5.4 |
| Reproducibility SD as a % of the Mean | 6.0% | 8.9% |
| Reproducibility Limit | 11.4 | 15.2 |
| ***Reproducibility Ratio (CEM-530/CELLCHEK PLUS)*** | ***0.7466*** | |
| **Central Corneal Thickness** | | |
| Repeatability SD | 3.3 | 12.5 |
| Repeatability SD as a % of the Mean | 0.6% | 2.2% |
| Repeatability Limit | 9.2 | 34.9 |
| ***Repeatability Ratio (CEM-530/CELLCHEK XL (PLUS))*** | ***0.2634*** | |
| Reproducibility SD | 5.8 | 13.2 |
| Reproducibility SD as a % of the Mean | 1.1% | 2.3% |
| Reproducibility Limit | 16.3 | 37.0 |
| ***Reproducibility Ratio (CEM-530/CELLCHEK PLUS)*** | ***0.4414*** | |

Additional analysis was completed on 24 images with and without corneal pathology using both the manual method and automated method of analysis on the same image. The images were then analyzed and generated the following results for CD (Cell Density), CV(Coefficient of Variation) and HEX(%Hexagonality)

**Table 3: Agreement Analysis on Same Image – Automated vs. Manual Method**

| | CD (Cell Density) | CV (Coefficient of Variation) | HEX (Hexagonality) | NUM (Number of Cells) |
|---|---|---|---|---|
| **Mean** | 2267.2 / 2165.3 Auto / Manual | 28.9 / 36.3 Auto / Manual | 68.7 / 57.4 Auto / Manual | 173.3 / 153.3 Auto / Manual |
| **Mean Difference (SD)** | 101.9 (53.76) | -7.4(4.91) | 11.3(7.75) | |
| **Mean difference as a % of the Manual reading** | 4.94% | -19.41% | 20.98% | 13.47% |
| **Correlation (R^2)** | 0.9918 | 0.7523 | 0.2226 | 0.4306 |
| **Deming Regression Intercept** | 127.7 | 5.0 | 50.3 | -334.1 |
| **Deming Regression Slope** | 1.0 | 0.7 | 0.3 | 3.3 |

**Figure 14: Deming Regression Plot – CEM-530 by Manual – Endothelial Cell Density (CD) – Same Image – All Subjects**

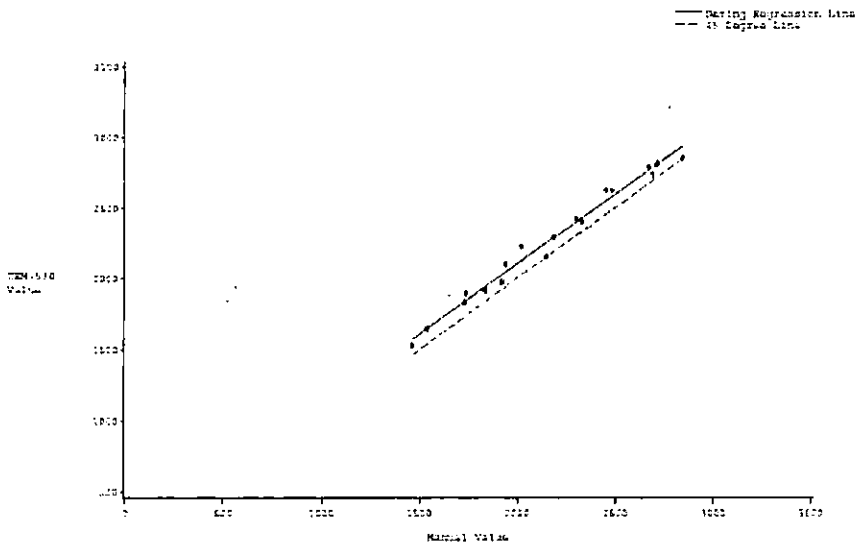


**Figure 15: Deming Regression Plot – CEM-530 by Manual – Coefficient of Variation of Endothelial Cell Area (CV) – Same Image – All Subjects**

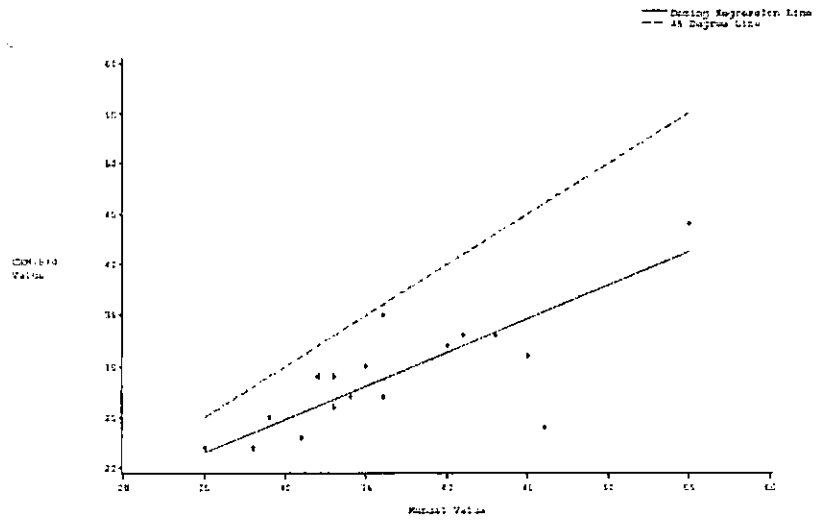
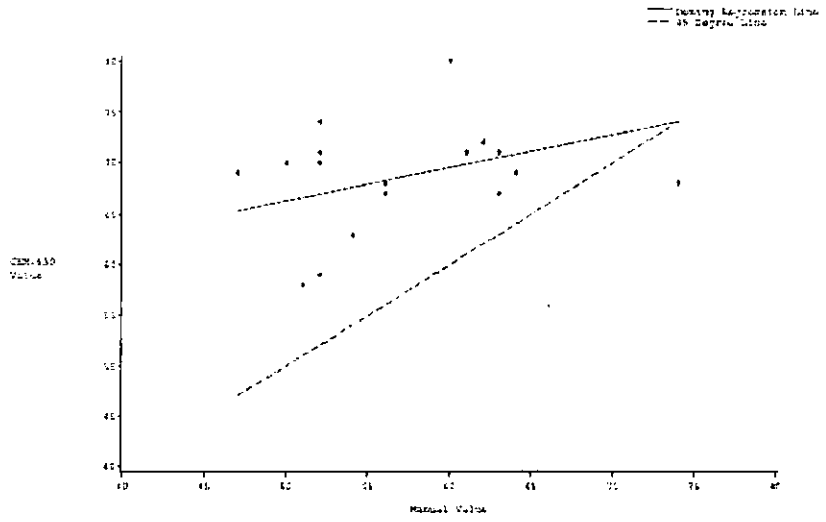


**Figure 16: Deming Regression Plot – CEM-530 by Manual – % Hexagonality (HEX) – Same Image – All Subjects**



In summary, the agreement and precision of the Nidek CEM-530 was found to be substantially equivalent to the predicate device.

**CONCLUSIONS**

The Nidek Specular Microscope CEM-530 has the same intended use and indications for use, technological characteristics, and principles of operation as the previously cleared predicate. The minor differences between the subject device and the predicate device have been assessed in a human clinical trial which found agreement, accuracy and precision between the two devices. Therefore, the Nidek Specular Microscope CEM-530 is as safe and effective as its predicate device, and thus, substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 27, 2013

Nidek Co., Ltd.
c/o Mr. Aron Shapiro
Vice President
300 Brickstone Square
Andover, MA 01810

Re: K130565
Trade/Device Name: Nidek Specular Microscope CEM-530
Regulation Number: 21 CFR 886.1850
Regulation Name: AC-Powered Slitlamp Biomicroscope
Regulatory Class: Class II
Product Code: NQE
Dated: October 17, 2013
Received: October 18, 2013

Dear Mr. Shapiro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K130565

Device Name: Nidek Specular Microscope CEM-530

Indications For Use:

The Nidek Specular Microscope CEM-530 is a non-contact ophthalmic microscope, optical pachymeter, and camera intended for examination of the corneal endothelium and for measurement of the thickness of the cornea.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

Marsha L. Burke Nicholas -S
2013.12.03 15:14:38 -05'00'